

K962306

AUG 29 1996

510(k) Summary

- a.1. Diagnostic Hybrids, Inc.
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Athens, OH 45701
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Attn: J.L. Brown
Date of Preparation: June 10, 1996
- a.2. Trade Name: **FreshCells™**
Classification Name: Cells, Animal and Human, Cultured.
- a.3. A predicate device is that of BioWhittaker, marketed as cell cultures, Appendix II, p.18 of this 510(k) Notification.
- a.4. The subject device provides A549 cells as nearly confluent monolayers ready for use upon receipt after a short pre-incubation period.
- a.5. Intended Use: Cell cultures to be used for specific virus isolation and identification. The subject of this 510(k) Notification, the cell line, A549, is susceptible to and can be used in the isolation and confirmation of the following viruses from clinical samples:

Adenovirus	Parainfluenza
HSV	Poliovirus
Influenza	RSV
Measles	Rotavirus
Mumps	

- a.6. A comparison of Technological Characteristics:

<u>Characteristics</u>	<u>Predicate Device</u>	<u>Subject Device</u>
Source of Cell Line.	ATCC or another approved supplier.	Same as predicate device.
Provided as nearly confluent monolayers.	Cells are provided routinely as nearly confluent monolayers.	Same as predicate device.
Intended Use.	Isolation & Confirmation of specific viruses.	Same as predicate device.

- b.1. The non-clinical tests consist of those used to characterize the product such as appearance, growth characteristics, sterility, isoenzyme analysis and virus susceptibility.
- b.2. Not applicable.
- b.3. Not applicable.